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DRAFT -- September 25, 1987

COMMENTS OF THE TOBACCO INSTITUTE IN OPPOSITION TO PETITION FOR AN EMERGENCY TEMPORARY STANDARD PROHIBITING INDOOR WORKPLACE SMOKING

The Tobacco Institute submits these comments in opposition to the petition of Public Citizen Health Research Group and the American Public Health Association ("petitioners") filed on May 6, 1987.[1/] Petitioners request the Occupational Safety and Health Administration ("OSHA") to promulgate an emergency temporary standard pursuant to section 6(c) of the Occupational Safety and Health Act of 1970 ("OSH Act"), 29 U.S.C. § 655(c), that would prohibit smoking in all indoor workplaces, except in limited designated smoking areas.

As demonstrated in these comments, the relief sought by petitioners is unwarranted. The scientific evidence purportedly linking environmental tobacco smoke with adverse health effects is meager, contradictory and fundamentally flawed. In fact, the available evidence justifies neither the extraordinary step of imposing an emergency temporary standard nor promulgation of a permanent standard.

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1/ The Tobacco Institute, headquartered in Washington, D.C., is a national trade association representing major United States cigarette manufacturers.

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I. INTRODUCTION

The standard sought by petitioners, to be imposed without notice-and-comment rulemaking, would prohibit smoking in all indoor workplaces, including motor vehicles, except in designated smoking rooms with separate ventilation systems. In addition, employers would be required to establish smoking policies, to resolve all smoking disputes in favor of non-smokers, and to provide smoking cessation programs to employees who desire them.

Relying principally on recent reviews of the scientific literature by the Surgeon General[2/] and the National Academy of Sciences,[3/] petitioners assert that nonsmokers exposed to environmental tobacco smoke are at increased risk of developing lung cancer. Petitioners also claim that environmental tobacco smoke causes other adverse health effects in nonsmokers, such as other cancers, heart disease and chronic lung disease.

The evidence cited in the petition does not establish either a "grave danger" or a "significant risk" of adverse health effects from workplace exposure to

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2/ U.S. Surgeon General, The Health Consequences of Involuntary Smoking (1986) (hereinafter "Surgeon General's Report").

3/ National Academy of Sciences, Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects (1986) (hereinafter "NAS Report").

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environmental tobacco smoke. Accordingly, there is no justification for a federal prohibition or restriction on smoking in the workplace.

II. AN EMERGENCY TEMPORARY STANDARD IS UNWARRANTED

Under section 6(c) of the OSH Act, an emergency temporary standard can be promulgated only if OSHA determines that (A) "employees are exposed to a grave danger" from toxic substances or from "new hazards" and (B) an emergency standard is "necessary to protect" the employees. 29 U.S.C. § 655(c)(1). OSHA must publish a statement of reasons for its actions under section 6, 29 U.S.C. § 655(e), and its determinations must be supported by substantial evidence in the record taken as a whole. 29 U.S.C. § 655(f). E.g., Dry Color Manufacturers' Association v. Department of Labor, 486 F.2d 98, 101 (3d Cir. 1973).

An emergency temporary standard must be employed with extreme caution. In every reported case involving an OSHA emergency standard, the reviewing court has either vacated the standard,[4/] stayed the standard's effect [5/] or

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4/ United Automobile Workers v. Donovan, 590 F. Supp. 747, 750 (D.D.C. 1984); Florida Peach Growers Ass'n v. Dep't of Labor, 489 F.2d 120, 129 (5th Cir. 1974); Dry Color Manufacturers' Ass'n v. Dep't of Labor, 486 F.2d 98, 101 (3d Cir. 1973).

5/ Asbestos Information Ass'n of North America v.
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refused to require the Secretary to promulgate a standard.6/ The emergency standard has been characterized as an "extraordinary" remedy (Taylor Diving & Salvage Co. v. Department of Labor, 537 F.2d 819, 820 (1976)), which "should be delicately exercised, and only in those emergency situations which require it." Florida Peach Growers Association v. Department of Labor, 489 F.2d 120, 129 (5th Cir. 1974). Accord, United Automobile Workers v. Donovan, 590 F. Supp. 747, 750 (D.D.C. 1984); Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1155 (D.C. Cir. 1983). An emergency temporary standard is the "most drastic measure" available to the Secretary. Asbestos Information Association of North America v. Occupational Safety and Health Administration, 727 F.2d 415, 426 (5th Cir. 1984), Public Citizen, 702 F.2d at 1152. It is appropriately employed, as a consequence, only as "an unusual response to exceptional circumstances." Dry Color Manufacturers, 486 F.2d at 104.

Section 6(c) does not regulate every danger, or even every significant danger. Rather, its application is limited to "grave" dangers. Minimal or undefined risks, or the mere

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Occupational Safety and Health Administration, 727 F.2d 415, 426 (5th Cir. 1984); Taylor Diving & Salvage Co. v. Dep't of Labor, 537 F.2d 819, 820 (5th Cir. 1976).

6/ Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1155 (D.C. Cir. 1983).

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possibility of injury, do not rise to the level of a "grave" danger. Florida Peach Growers, 489 F.2d at 130. As explained in the Dry Color Manufacturers case, 486 F.2d at 104 (footnote omitted):

> [W]hile the Act does not require an absolute certainty as to the deleterious effect of a substance on man, an emergency temporary standard must be supported by evidence that shows more than some possibility that a substance may cause cancer in man.

Accord, Florida Peach Growers, 489 F.2d at 130-31. Extrapolations from old data and theoretical risk assessments are likewise insufficient, especially where no evidence or cases of actual injury are presented. Florida Peach Growers, 489 F.2d at 131; Dry Color Manufacturers, 486 F.2d at 103.

Six months is the maximum time period during which an emergency temporary standard can remain in effect. Accordingly, petitioners have the burden of establishing both that exposure to environmental tobacco smoke poses a grave danger and that such danger will arise during the limited timeframe of an emergency standard. An emergency temporary standard also must be supported by persuasive evidence that a grave danger will arise under actual working conditions, as distinct from theoretical or worst case exposure assumptions. United Automobile Workers, 590 F.Supp. at 751; Asbestos Information, 727 F.2d 418.

On February 27, 1987, OSHA Assistant Secretary John Pendergrass denied a petition by David Horne to ban tobacco

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smoke from the workplace. Assistant Secretary Pendergrass ruled that there was insufficient evidence to demonstrate a significant, quantifiable risk from workplace exposure to tobacco smoke. Nothing has occurred since that decision that would justify a different conclusion. In fact, the Public Citizen petition falls far short of the requirements that must be met for issuance of an emergency temporary standard. Specifically, a review of the studies cited by petitioners, and of important studies that petitioners have ignored, confirms that workplace exposure to environmental tobacco smoke does not involve a grave danger of lung cancer or any other adverse health effect.

A. The Alleged Danger of Lung Cancer Is Merely Speculative

The core allegation of the petition is that exposure to environmental tobacco smoke has been shown to increase the risk of lung cancer among nonsmokers. To support that allegation, petitioners rely primarily upon the reports of the Surgeon General and NAS. Petitioners' reliance upon those reviews is misplaced.

First, neither report establishes a relationship between lung cancer and exposure to environmental tobacco smoke in the workplace. Rather, both reports focus on exposure to tobacco smoke in the home. Second, both reports

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emphasize critical limitations on their finding of a possible connection between exposure to environmental tobacco smoke and lung cancer. Third, the vast majority of epidemiologic studies considered in the two reports involved non-United States populations. Extrapolation of the results of those studies to United State populations is subject to serious question on numerous grounds. Finally, even the limited conclusions of the reports have been severely criticized. Other recent reviews of the same literature have reached different conclusions, and the individual studies relied upon in the two reports are fundamentally flawed.

A critical flaw in the petition is the failure to cite persuasive evidence of a relationship between exposure to environmental tobacco smoke in the workplace and lung cancer. Both the Surgeon General and NAS reports acknowledge that most of the pertinent studies focus on long-term exposure to environmental tobacco smoke in the home rather than in the workplace. The NAS, in particular, was careful to point out important differences in home and workplace environments that make extrapolation from one to the other inappropriate. The NAS Report (p. 7) summarized this major shortcoming as follows:

> Most epidemiologic studies of chronic health effects have been conducted on persons who have had long term exposures to ETS from household members. The studies do not directly address chronic health effects in individuals who are

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exposed at work or have occasional exposures in the home or elsewhere.

Furthermore, as noted in the NAS Report (pp. 227-229), the few lung cancer studies that have focused on the workplace have failed to establish any relationship between exposure to environmental tobacco smoke and lung cancer. Of the three studies reviewed by the NAS that involved workplace exposure to environmental tobacco smoke, none can be said to have demonstrated an increased risk of lung cancer. Lee, P., et. al., British Journal of Cancer, vol. 54, pp. 97-105 (1986); Koo, L., et. al., International Journal of Cancer, vol. 39, pp. 162-169 (1987); Kabat, G. and Wynder, E., Cancer, vol. 53, pp. 1214-1221 (1984).7/

In short, the great majority of studies reviewed in the NAS Report do not involve workplace exposure. NAS Report at 10. Accordingly, neither the NAS Report nor that of the Surgeon General (which contains a review of essentially the same studies) is sufficient to satisfy the legal requirement

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7/ Although Kabat and Wynder found a "just statistically significant" increase in lung cancer incidence among men, they stressed that the small number of subjects involved, as well as other factors (including the fact that no increase was found among women), do not permit any definitive conclusions.

They further pointed out that "the difference between exposure to cigarette smoke at work between male cases and controls could be due to information bias" (p. ___).

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of demonstrating a grave risk under actual workplace conditions.

Similarly, the petition fails to satisfy the requirement of establishing a quantifiable risk from workplace exposure to tobacco smoke. As OSHA recognized in its February 1987 denial of the Horne petition on workplace smoking, demonstration of a significant, quantifiable risk is a prerequisite to any workplace exposure standard. The NAS and Surgeon General's conclusions concerning environmental tobacco smoke and lung cancer were expressly qualified in this respect. While the Surgeon General stated that environmental tobacco smoke "can cause lung cancer," Surgeon General's Report at 13, he also concluded that insufficient data exist "to accurately estimate the magnitude of risk." Ibid. See also id. at 36, 96, 101. The conclusions in the NAS report were similarly limited. NAS at 245-46. Thus, viewed most favorably to petitioners, the risk of lung cancer described in the Surgeon General and NAS reports is undefined and is, therefore, an inadequate basis of regulation.

In fact, only two quantitative risk assessments are cited in the petition, and they are insupportable. The numbers attributed to the NAS were taken from a risk assessment appended to the NAS Report, which was not considered or endorsed by the NAS committee and not reviewed by the National Research Council. NAS Report at 294. Moreover, this risk

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assessment was based on a number of theoretical assumptions that are open to serious question.

The second risk assessment cited in the petition, by Repace and Lowrey, is similarly flawed. It was termed "crude" upon evaluation by the Carcinogen Assessment Group of the Environmental Protection Agency. The Office of Technology Assessment also has been highly critical of Repace and Lowrey's work:

> Some of Repace and Lowrey's assumptions are inappropriate. In particular, in the method yielding the higher number, they assume that the entire difference between the lung cancer death rate in a group of nonsmoking Seventh-Day Adventists and in a group of nonsmoking (nonSeventh-Day Adventists) was attributable to passive smoking. Mortality rates for cancers at other sites are also lower in that Seventh-Day Adventists population, and the exact reasons for the differences are not known. Seventh-Day Adventists clearly have a low overall lung cancer death rate because there are few smokers in the population. Repace and Lowrey assume a lower rate of passive smoking than in the general population as well, which is probably justified. However, they use no specific information about the rate of passive smoking in either population they compared. At best, one can conclude that some part of the difference between the two populations may be due to differences in passive smoking rates, but the assumption that it is reasonable to attribute the entire difference to passive smoking is unjustified. The effect of these and other flaws on the final estimates calls into question the reliability of either of these numbers.

Office of Technology Assessment, 1986, pp. 21-22. The validity of the Repace and Lowrey risk assessment and conclusions

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has been strongly challenged elsewhere in the scientific literature for inappropriate methodology, unjustified assumptions, bias and selective manipulation of data.8/

A further fundamental weakness of the petition is its heavy reliance upon epidemiologic studies of foreign populations. Such studies, even if valid, are of insufficient relevance to warrant regulation of United States workers. As recognized in the NAS Report, data on lung cancer mortality in foreign populations is of limited relevance to United States populations for a variety of reasons, including differences in living conditions, genetic factors, cultural factors, health habits, diet, nutrition, health attitudes, risk taking, socioeconomic factors, occupational exposures, living space, population density, levels of indoor ventilation, and levels and nature of indoor air pollutants.9/ When the NAS combined the epidemiologic studies on Untied States populations, it found no increased risk of lung cancer. NAS Report, figure

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8/ Kilpatrick, S., Environment International (1986); Burch, P., Environment International (1986); Lebowitz, M., Environment International (1986); Arundel, A. et al., Journal Environmental Sciences and Health, (1986); Balter, N. et al., Proceedings 79th Annual Meeting of the Air Pollution Control Association (1986); Crawford, W., Environment International (1987).

9/ Indeed, only two of the thirteen studies reviewed in the NAS Report showed a statistically significant increase in lung cancer, an increase that was limited to nonsmoking spouses of smokers. NAS Report, Table 12-4, pp. 232-233. Both of those studies were of non-United States populations.

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12-1, page 234. That fact alone requires that the present petition be rejected.

Finally, it is important to note that even the limited conclusions of the Surgeon General and NAS Reports with respect to environmental tobacco smoke and lung cancer have been strongly criticized, and other reviewers have reached different conclusions from the same data. Viewing the same evidence considered by the NAS and Surgeon General, the International Agency for Research on Cancer of the World Health Organization concluded, also in late 1986, that the available evidence is consistent with a finding of no increase in risk -- either inside or outside the United States.10/ Many other reviewers, both from the United States and abroad, also have concluded that no causal relationship has been shown between ETS and adverse health effects.11/

10/ World Health Organization, International Agency for Research on Cancer, IARC Monograph on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking, vol. 38, p. 308 (1986).

11/ E.g., Kilpatrick, J., Toxicology Letters, vol. 35, pp. 163-68 (1987); Mantel, N., British Medical Journal, vol. 294, pp. 440-41 (1987); Crawford, W.A., The Medical Journal of Australia, vol. 146, pp. 174-75 (1987); Lee, P., et al., British Journal of Cancer, vol. 54, pp. 97-105 (1986); Lebowitz, M., Environmental International, vol. 12, pp. 3-9 (1986); Pershagen, G., Archives of Toxicology Supplement, vol. 9, pp. 63-73 (1986); Burch, P., British Medical Journal, vol. 293, p. 1053 (1986); Balter, N., et al., Air Pollution Control
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The many reviewers who have concluded that no relationship has been shown between environmental tobacco smoke and adverse health effects have emphasized a number of widely acknowledged deficiencies in the individual studies underlying the Surgeon General and NAS reports. These have recently been described in a detailed analysis by Professor Pershagen.12/ He demonstrates that both random and systematic errors are contained in a number of the studies, leading to his conclusion that: "These errors more or less severely affect the studies on passive smoking and lung cancer, and it should be kept in mind that most of them were not originally designed to study this relationship" (id. at 67).

Pershagen's paper was published the same year as the Surgeon General and NAS reports. He is a respected investigator who has personally conducted relevant epidemiological studies and reviewed the same data base as the Surgeon General and the NAS committee. Against this background, it is important to note that Pershagen concluded that:

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Ass'n: Proceedings of the 79th Annual Meeting, Paper 86-80.9 (1986); Witorsch, P., New Zealand Journal of Medicine, vol. 813, pp. 865-66 (1986); Blot, W., et al., Journal of the National Cancer Institute, vol. 77, pp. 993-10000 (1986); Kuller, L., Environmental Health Perspectives, vol. 70, pp. 57-69 (1986).

12/ Pershagen, G., Archives of Toxicology Supplement, vol. 9, pp. 63-73 (1986).

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"Taken together, the epidemiological evidence does not seem sufficient to conclude that exposure to environmental tobacco smoke causes lung cancer." Ibid.

The significance of the deficiencies noted by Pershagen and others can be most readily appreciated by focusing on the Hirayama study -- the study with the greatest quantitative effect on the NAS aggregate analysis of worldwide epidemiologic results. The Hirayama study purports to assess the incidence of lung cancer in nonsmoking spouses of smokers, as compared to nonsmoking spouses of nonsmokers, in Japan. Hirayama, T., British Medical Journal, vol. 282, pp. 183-185 (1981); Preventive Medicine, vol. 13, pp. 680-90 (1984). Not only are there many major confounding variables between Japanese and United States populations, but the Hirayama study has been widely criticized in the scientific literature for a number of potentially invalidating flaws, including lack of adequate exposure verification, absence of histopathological confirmation of lung cancer diagnosis and other significant methodological and analytical deficiencies.13/ If the

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13/ Lee, P., et. al., British Journal of Cancer, vol. 54, pp. 97-105 (1986); Lebowitz, M., Environmental International, vol. 12, pp. 3-9 (1986); Pershagen, G., Archives of Toxicology Supplement, vol. 9, pp. 63-73 (1986); MacDonald, E., British Medical Journal, vol. 283, pp. 1465-1466 (1981). Kastenbaum, M., Lancet, vol. 1, p. 1406 (1984); Kornegay, H. and

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Hirayama study is excluded because of its weaknesses, but other studies of non-United States populations are considered, an aggregate analysis -- such as that conducted by the NAS -- produces a finding of no increased risk of lung cancer among nonsmokers. In other words, such analysis simply confirms the results of studies of United States populations.

In sum, there are multiple independent deficiencies in the evidence purportedly linking exposure to environmental tobacco smoke and lung cancer. Even if those deficiencies are ignored, the fact remains that the available evidence does not establish a significant or quantifiable risk of lung cancer in United States populations exposed to tobacco smoke in the workplace.

B. The Evidence Fails To Support Claims of Other Adverse Health Effects

There also has been no showing of grave danger or significant risk of other adverse health effects from workplace exposure to environmental tobacco smoke. The petition posits a wide range of effects -- non-lung cancers,

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Kastenbaum, M., British Medical Journal, Vol. 283, p. 914 (1981).

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non-cancer lung disease and cardiovascular effects -- none of which have been established scientifically.

The Surgeon General's Report itself rejected the claim that a relationship has been shown between exposure to environmental tobacco smoke and an increased risk of adult cancers other than primary carcinoma of the lung. Surgeon General's Report at 104. The NAS Report reached the same conclusion. NAS Report at 255.

With respect to the purported reduction in lung function, after careful review of the literature -- including the White and Froeb and Kauffman studies cited by petitioners -- the NAS concluded:

> Three studies have shown a small reduction in pulmonary function in normal adults exposed to ETS. Interpretation of these findings is difficult because pulmonary effects in normal adults are likely to reflect the cumulative burden of many environmental and occupational exposures and other insults to the lung. Thus, the effects of ETS on the lungs of adults are likely to be confounded by many other factors, making it difficult to attribute any portion of the effect solely to ETS.

NAS Report at 10. The Surgeon General's analysis was similar:

> Several studies have reported small decrements in the average level of lung function in nonsmoking adults exposed to ETS. These differences may represent a response of the lung to chronic exposure to the irritants in ETS, but it seems unlikely that ETS exposure by itself is responsible for a substantial number of cases of clinically significant chronic obstructive lung disease.

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Surgeon General's Report at 10. Importantly, the Surgeon General also concluded that:

> The physiologic and clinical significance of the small changes in pulmonary function found in some studies of adults remains to be determined. The small magnitude of effect implies that a previously healthy individual would not develop chronic lung disease solely on the basis of involuntary tobacco smoke exposure in adult life.

Surgeon General's Report at 62.

Similar conclusions were reached by Pershagen, who noted:

> It may be concluded that exposure to environmental tobacco smoke only has minor, if any, effects on pulmonary function in normal subjects. Functional effects of this magnitude would not be of clinical importance. Pershagen, G., Archives of Toxicology, Supplement, vol. 9, pp 63-73 (1986).

Other studies, not cited in the petition, have failed to demonstrate an adverse effect of environmental tobacco smoke on pulmonary function in adults.[14/] There is thus no basis for finding that environmental tobacco smoke poses any risk of loss of pulmonary function.

14/ Comstock, G. et al., American Review of Respiratory Disease, vol. 124, pp. 143-48 (1981); Kentner, M. et al., Preventive Medicine, vol. 13, pp. 656-69 (1984); Schilling, R. et al., American Journal of Epidemiology, vol. 106, pp. 274-83 (1977); Lebowitz, M., Preventive Medicine, vol. 13, pp. 645-55 (1984).

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Finally, no link has been shown between environmental tobacco smoke and cardiovascular disease. The Garland and Aronow studies relied upon by the petitioners are severely flawed and have been rejected by most researchers, including the Surgeon General and NAS. Surgeon General's Report at 106; NAS Report at 263-264.15/ As to the overall question of the putative relationship between cardiovascular disease and environmental tobacco smoke, the Surgeon General's Report stated:

> "Further studies on the relationship between involuntary smoking and cardiovascular disease are needed in order to determine whether involuntary smoking increases the risk of cardiovascular disease." Surgeon General's Report at 14.

The NAS reached a similar conclusion. As stated in the NAS Report:

> "Reports have noted an excess risk of cardiovascular disease in ETS-exposed nonsmokers; however, methodological problems in the designs and analyses of these studies preclude any firm conclusions about the results. Studies reporting that ETS can precipitate the onset of angina pectoris among people who already have this condition are subject to the

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15/ See also Wakehan, H., New England Journal of Medicine, vol. 299, p. 896 (1978); Robinson, B., New England Journal of Medicine, vol. 299, p. 896 (1978); Waite, C., New England Journal of Medicine, vol. 299, p. 897 (1978); Coodley, A., New England Journal of Medicine, vol. 299, p. 897 (1978). Aronow was cited by a federal regulatory agency for falsification of data and his data on carbon monoxide levels was rejected as questionable by another federal regulatory agency. Schievelbein, H. and Richfer, F., Preventive Medicine, vol. 13, pp. 626-644 (1984).

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> same precautionary note. Exposure to ETS produced no statistically significant effects on heart rate or blood pressure in school age children or healthy adult subjects, either during exercise or at rest. Data are not available as to possible adverse cardiovascular effects in susceptible populations, such as infants, elderly, or diseased individuals.

NAS Report at 11. In short, most of petitioners' health-related claims have been rejected by both the Surgeon General and the National Academy of Sciences, and provide a clearly inadequate basis for regulation by OSHA.

C. A Grave Danger Will Not Arise Within Six Months

An emergency temporary standard remains in effect for only six months,[16/] after which a permanent standard must be put in place. Consequently, the case law is clear that an emergency temporary standard must be supported not only by a showing of "grave danger" but also by demonstration that the grave danger will arise within the six month period covered by the standard. As emphasized by the Court in the Asbestos Information Association case, 727 F.2d at 422:

> [Section 6(c)] is not to be used merely as an interim relief measure . . .. The Agency cannot use its [emergency temporary standard] powers as a stop-gap measure.

16/ The emergency standard is effective until a permanent standard is promulgated after notice-and-comment rulemaking, 29 U.S.C. § 655(c)(2), and the Secretary must promulgate a permanent standard within six months after publication of the temporary standard. 29 U.S.C. § 655(c)(3).

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Petitioners have not only failed to establish a grave danger from environmental tobacco smoke but have failed to show that any such danger would arise in six months.

D. There Is No Evidence of a Grave Danger at Actual Workplace Exposure Levels

An emergency temporary standard must be supported by evidence of a grave danger under actual workplace conditions. United Automobile Workers, 590 F. Supp at 751; Asbestos Information Association, 727 F.2d at 418; Dry Color, 486 F.2d at 104. Theoretical or worst case exposure assumptions are an insufficient basis for an emergency standard. Florida Peach Growers, 489 F.2d at 130. In each of the cited cases, the regulated substance was shown to be toxic at high levels but the reviewing court found that the Agency lacked evidence that actual workplace exposure levels presented a grave danger.

Petitioners have not shown that exposure of employees to environmental tobacco smoke under actual workplace conditions poses a grave danger. The petition would ban all workplace smoking, regardless of workplace conditions, levels of tobacco smoke, extent of ventilation and other relevant factors. The petition plainly fails to justify the requested relief.

As noted, the studies relied upon by petitioners do not involve workplace conditions. All of the putatively positive epidemiological studies are spousal studies. As

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indicated above, those studies have not been shown to be applicable to workplace exposure. As between home and workplace environments, there are likely to be differences in the intensity and duration of exposure to tobacco smoke, level of exposure to other indoor air pollutants, adequacy of ventilation and other factors. These factors are critical to the petition, yet none of the available studies control for them.

Petitioners have presented no evidence of employee disease or injury from exposure to environmental tobacco smoke under workplace conditions. Indeed, even the Surgeon General has characterized the few available studies involving workplace conditions as "limited and inconclusive." Surgeon General's Report at 91. Environmental tobacco smoke in the workplace is highly dependent upon the physical arrangement of the work environment, breathing patterns, filtration, and adherence of smoke particles to room surfaces. See id. at 11-12, 135-44, 167. Consequently, petitioners can neither quantify the overall risk of environmental tobacco smoke nor assess its effect in the workplace.

E. A Ban On Workplace Smoking Is Not Necessary To Prevent Any Potential Danger

The further prerequisite to an emergency temporary standard is that it be "necessary to protect employees." 29 U.S.C. § 655(c)(1)(B). This imposes upon the Agency a requirement to consider feasible alternatives to the proposed

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regulatory action. See, e.g., Dry Color Manufacturers, 486 F.2d at 107. OSHA must have "proved that the [emergency temporary standard], OSHA's most dramatic weapon in its enforcement arsenal, is 'necessary' to achieve the projected benefits." Asbestos Information Association, 727 F.2d at 426. Petitioners have made no showing that a ban on workplace smoking is necessary to prevent the purported dangers of environmental tobacco smoke.

An obvious alternative, which petitioners summarily reject, is improved ventilation. Ventilation is clearly an important variable in workplace exposure. Surgeon General's Report at 11-12. Good ventilation systems can reduce indoor air contaminants, including ETS, to negligible levels. Petitioners claim, without foundation, that ventilation does not reduce exposure to tobacco smoke. But experts in ventilation such as Gray Robertson, president of a company specializing in indoor air pollution, have found otherwise. In a presentation to the NAS committee, Mr. Robertson explained that numerous steps can be taken to improve the ventilation in most buildings. Assuring the introduction of filtered outside air, maintaining effective filtration systems, ongoing monitoring of air quality, cleaning and repairing ductwork and improving the designs of ventilation systems are practical steps for the achievement of acceptable indoor air quality.

Improved ventilation can also reduce the levels of a multitude of other indoor pollutants. These include gases and

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particulate matter, and bacteria and fungi. Studies by ventilation experts have shown that such pollutants, if present in sufficient concentrations, can result in widespread allergies and other respiratory complaints. These problems are primarily caused by the microorganisms in the indoor environment and not by tobacco smoke. Cleaning and upgrading of ventilation systems has eliminated the illnesses while permitting employees to continue to smoke.

Petitioners have failed to address alternatives to a ban on indoor workplace smoking, as required by section 6(c). There has been no showing that the requested relief -- essentially a complete ban on workplace smoking -- would provide significantly greater protection than improved ventilation.

The requested ban on workplace smoking is undesirable for several additional reasons. First, it would unreasonably restrict employee freedom. The choice to smoke or not is a personal decision, which has traditionally -- and rightly -- been left to the individual employee. Second, a ban would impose an unnecessary burden on workers who smoke. Third, the requested ban on workplace smoking is inconsistent with the strong preference in the OSH Act and regulations for engineering controls over work practice restrictions, which raise difficult and unavoidable issues of supervision, employee motivation, monitoring and appropriate penalty procedures.

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III. A PERMANENT STANDARD CANNOT BE JUSTIFIED

In addition to not justifying an emergency order, the available scientific evidence cannot support a permanent standard banning indoor workplace smoking pursuant to 29 U.S.C. § 655(b)(5). The Supreme Court held in the Benzene case that the OSH Act "was not designed to require employers to provide absolutely risk-free workplaces." Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 641, 647 (1980) (plurality). Rather, OSHA may regulate only on the basis of "significant risks of harm." Id. at 641-42, 655. The burden is squarely on the proponent of the standard to show that the existence of a risk is more likely than not, id. at 653, based on the best available evidence. Id. at 656.

OSHA recognized in its February 27, 1987, denial of the Horne petition to ban workplace smoking that "when possible, the Agency must perform a quantitative risk assessment of any suspect carcinogen before the Agency can regulate it." Current data provide no basis for such a risk assessment. As discussed above, the Surgeon General and NAS reports expressly stated that no overall risk calculations for environmental tobacco smoke can be reliably made. Moreover, as shown above, the studies cited in the NAS and Surgeon General Reports are fundamentally flawed, inconsistent and largely irrelevant to actual workplace exposure of United States populations.

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IV. CONCLUSION

There is no persuasive evidence that environmental tobacco smoke presents a significant health risk. Nor has it been shown that actual workplace levels of ETS are hazardous. In any event, there are alternative measures, including improved ventilation, that would reduce workplace exposure to indoor pollutants (including toxic pollutants unrelated to tobacco smoke) without the disruption and infringement on worker freedom of a smoking ban. For these reasons, the petition should be denied.

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